REMARKS

Applicant's attorney is appreciative of the interview granted by Examiners Richter and Sullivan on June 25, 2009. At that interview, Applicant's attorney proposed amendments to the specification and claims which the Examiners agreed would remove the formality rejections, and further proposed amendments to the claims to distinguish over the prior art.

Objection has been raised to the specification on the basis of improper incorporation of material by reference. The specification has now been amended so that the reference to PCT Publication WO 01/62256 has been replaced by a reference to U.S. Patent Publication 2003/0045522. It is noted that U.S. Patent Publication 2003/0045522 was filed as application No. 10/182,718, which was a filing under 35 USC 371 of PCT/EP01/02055, the application which was published as WO 01/62256. Since the U.S. patent publication is thought to constitute an exact translation into English of the PCT publication, no new matter is added by this amendment to the specification.

Claims 1, 2 and 6-12 have been rejected under 35 USC 112, 1st paragraph, as failing to comply with the enablement requirement in the claiming of a method of preventing atherosclerosis. Claim 1 has now been amended to recite only a method for attenuating development of atherosclerosis, and it was agreed at the interview that this amendment would overcome the rejection for lack of enablement.

A separate rejection of Claims 2, 6, 8, 11 and 12 has been made under 35 USC 112, 1st paragraph, as failing to comply with the written description requirement. This rejection is based upon the failure to properly incorporate the subject matter of the prior application by reference, and it was agreed at the interview that by amending the

specification to properly incorporate this prior application, the rejection would be overcome.

Withdrawal of this rejection is requested.

Claims 1, 2 and 6-12 have been rejected under 35 USC 103(a) over Geczy in view of Grodzinska et al.

Claim 1 has now been amended as discussed at the interview to recite that molsidomine or a pharmaceutical salt thereof is administered daily, for a period of at least six months, in the form of a sustained release oral composition containing between 14 and 24 mg of molsidomine effective over 24 hours. This amendment to Claim 1 is fully supported by the specification, the administration for at least 6 months being disclosed in paragraph [0027] of the published application, the dosage of between 14 and 24 mg being disclosed in paragraph [0039] of the published application, and the daily administration being disclosed in paragraph [0049] and [0052] of the published application.

The Geczy reference which has been cited in the rejection corresponds to the reference which has now been incorporated by reference into the present application. Geczy discloses controlled release of molsidomine for treatment of angina attacks, but does not disclose or suggest the advantages of long term administration for a different purpose which have been disclosed in the present application.

The Grodzinska et al reference discloses that molsidomine may activate the fibrinolytic system and inhibit platelet aggregation when administered for a period of several weeks to patients in the form of an infusion (2 mg/hour) for the first six days, combined with a daily oral intake of a pill containing 4 mg of molsidomine per day (divided into two doses). The treatment period is 2 to 4 weeks as opposed to the presently claimed 6 months, and the daily dosage is quite low, 4 mg as opposed to the daily claimed dosage of 14

to 24 mg, with extended release.

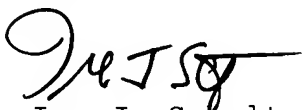
The present specification reports in detail on testing of the claimed invention, in comparison with prior art treatments involving molsidomine. Paragraph [0075] of the published application states that as shown in table 2, the four week treatment with molsidomine, even at a relatively high level of 16 mg o.a.d. or 8 mg b.i.d., had no effect on the level of circulating intercellular adhesion molecule-1 (ICAM-1). However, as reported in paragraph [0076], after 12 months of molsidomine treatment at 16 mg o.a.d., the level of ICAM-1 was substantially lower, compared with the baseline values before the study.

Thus, Applicant has discovered that long term, daily administration of higher levels of molsidomine makes it possible to restore endothelial functions, and makes it possible to prevent physio-pathological processes that lead to atherosclerosis when used in a very specific form, which is a sustained release oral composition. Nothing in the Grodzinska et al document, nor in the prior art taken as a whole, would lead a person of ordinary skill in the art from looking for a composition to treat atherosclerosis to use a specific galenical form of molsidomine containing a higher dosage for a long term treatment.

Accordingly, the combination of Geczy with Grodzinska et al does not disclose or suggest the invention, and withdrawal of this rejection is requested.

In view of the foregoing amendments and remarks, Applicant submit that the present application is now in condition for allowance. An early allowance of the application with amended claims is earnestly solicited.

Respectfully submitted,



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